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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,976	12/27/2005	John Simon Kroll	MSQ02-004-US	1346

43320 7590 11/02/2007
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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,976

Applicant(s)

KROLL ET AL.

Examiner

Nina A. Archie

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-60 is/are pending in the application.
- 4a) Of the above claim(s) 47 and 49-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-46 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/9/2005, 12/7/2005, 4/20/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

3. The information disclosure statement filed on 6/9/2005, 12/27/2005 has been considered. Initialed copies are enclosed.

Election/Restrictions

4. Applicant's election with traverse of Group I claim 41-46 and 48 in the reply filed on 7/16/2007 are acknowledged. According to PCT Rule 13.1 and 13.2. The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The traversal is on the ground(s) that the discrete subset of *A. pleuropneumoniae* genes involved in virulence defines the special technical feature linking the subject matter of claims 41-60 and is not taught or suggested by the prior art and the sequences of the pending claims (SEQ ID NOs: 1-56) represent a discrete subset of the *A. pleuropneumoniae* genome. Applicants also respectfully traverse the restriction

between SEQ ID NOs: 1-56, since the present application is a nationalization of a PCT application, restriction is allowed only under the Unity of Invention standard. This is not found persuasive.

The lack of unity dated on 6/14/2007 is based on the claims filed. The special technical feature of Group 1 is an attenuated *Actinobacillus pleuropneumoniae* bacterium. The technical feature of Group 1 is anticipated by Segers et al US Patent 6,783,764 August 31, 2004 (filing date August 31, 1999). Segers et al. teaches a attenuated *Actinobacillus pleuropneumoniae* bacterium (abstract column 4 lines 18-21, column 5 lines 22-35, column 6 lines 1-29). Therefore unity of invention is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claim 48 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 48 a dependent claim recites the phrase "moderate to high". However, neither the claim nor the specification clearly defines nor sets forth the meaning or means to assess "moderate to high". "Moderate to high" has no art defined meaning with respect to an attenuated bacteria. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of "moderate to high" nor how to assess such. It is unclear how to interpret what is considered "moderate" and inasmuch as it is not a recognized term and not defined in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 41-42 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuller et al 2000 Microbial Pathogenesis Vol. 29 pgs. 39-51.

Claims 41-42 and 44 are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium.

Fuller et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a single gene (see abstract, pg. 40 "Results Section", pg. 46 "Materials and Methods Section"). Fuller et al teach *Actinobacillus pleuropneumoniae* strain grown in Brain Heart Infusion media thus Fuller et al anticipate a composition comprising the bacterium of *Actinobacillus pleuropneumoniae* (see pg. 46 "Materials and Methods Section"), wherein the composition comprises bacteria having different mutations in the same virulence gene (see abstract, pg. 40 "Results Section", pg. 46 "Materials and Methods Section").

7. Claims 41-42 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Segers et al US Patent No. 6,013,266 Date January 11, 2000.

Claims 41-42 and 44 are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium.

Segers et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a single gene (see abstract, column 5 lines 55-65, see columns 11-14). Segers et al teach *Actinobacillus pleuropneumoniae* bacterium in a pharmaceutically acceptable carrier thus Segers et al anticipate a composition comprising the bacterium of *Actinobacillus pleuropneumoniae* (see column 8 lines 50-60 and column 5 lines 55-65, see columns 11-14), wherein the composition comprises bacteria having different mutations in the same virulence gene (see abstract, column 5 lines 55-65, column 8 lines 50-60, columns 11-14).

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8. Claims 41-42 and 44-46 are rejected under 35 U.S.C. 102(e) as anticipated by Lowery et al US 6,790,950 Date September 14, 2004 (US Filing Date March 15, 2001).

Claims 41 and 45-46 are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium.

Lowery et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a different genes (see abstract, column 3 lines 60-67, columns 4-6, column 7 lines 51-64, column 32 example 10). Lowery et al teaches a composition, comprising the bacterium of an attenuated *Actinobacillus pleuropneumoniae* bacterium, comprising a plurality of different attenuated *A. pleuropneumoniae* bacteria having different mutations in the same virulence gene (see abstract, column 3 lines 60-67, columns 4-6, column 7 lines 51-64, column 32 example 10).

Status of the Claims

9. No claims are allowed.

Claims 41-42, 44-46 are rejected.

Claims 43 and 48 are objected as being dependent on a base claim.

Conclusion

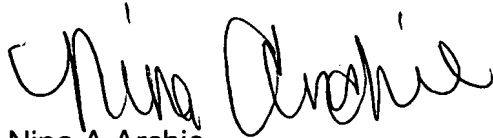
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.




Nina A Archie

Examiner

GAU 1645

REM 3B31



MARK NAVARRO
PRIMARY EXAMINER